

AK-



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/678,357	10/04/2000	Sven Mardh	SMAR.P001	4507
21121	7590	01/05/2006	EXAMINER	
OPPEDAHL AND LARSON LLP P O BOX 5068 DILLON, CO 80435-5068			SHAHNAN SHAH, KHATOL S	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 01/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	<b>Application No.</b> 09/678,357	<b>Applicant(s)</b> MARDH ET AL.	
	<b>Examiner</b> Khatol S. Shahnian-Shah	<b>Art Unit</b> 1645	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 28 October 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 31 October 2005. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: \_\_\_\_\_.  
 Claim(s) objected to: \_\_\_\_\_.  
 Claim(s) rejected: \_\_\_\_\_.  
 Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.  
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_.  
 13. ☐ Other: \_\_\_\_\_.

***Attachment to Advisory Action***

1. The Examiner of U.S. Patent application SN 09/678,357 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to Examiner Shahnan-Shah, Technology Center 1600, Art Unit 1645.
2. Currently claims 14-15, 18-30 and 32 are pending.
3. Applicants' Reply to a final office action, received 10/28/2005 is acknowledged.
4. Applicants' notice of appeal, received 10/31/2005 is acknowledged.

***Rejections Maintained***

5. Rejection of claims 14-15, 18-30 and 32 under 35 USC § 103(a) as being unpatentable over Oksanen et al. in view of Ma et al. is maintained for the reasons of record.

Applicants argue that independent claim 14 recites the steps of multiplying the level of pepsinogen I by the level of Helicobacter pylori antibodies to get a number, and comparing the number calculated similarly for the normal population. Applicants further argue that the examiner argues that calculating a ratio of indicators is obvious.

It is the examiner's position that in this case, the methods taught by Oksanen et al., and Ma et al., are capable of producing results which show varying levels of antibodies and pepsinogen

and allowing one of ordinary skill in the art to determine what those levels are indicative of since the references teach the comparison of blood test results and the indicativeness of

various forms of gastritis. Moreover, it is noted that generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by

the prior art unless there is evidence indicting such concentration or temperature is critical. "[W] here the general conditions of a claim are disclosed in the prior art, it is not inventive to

discover the optimum or workable ranges by routine experimentation." In re *Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a

temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only

Art Unit: 1645

In that the reference process was performed at a temperature of 100°C and an acid concentration Of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire

of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination

of percentages.") In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references

were held to be unpatentable there over because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more

recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989)', In re Kulling,

897 F.2d 1 147, 14 USPQ2d 1056 (Fed. Cir. 1990). Therefore, in the instant case, the examiner has provided support as to why the optimization limitations fail to provide a basis for

patentably, contrary to applicants' statements. It is also noted that applicant has failed to show that a particular range is critical, or show that the claimed range achieves unexpected

results relative to the prior ad range. Therefore in view of applicants' failure to claim critical ranges or show unexpected results, the rejection is maintained.

Therefore, contrary to applicants' assertions, the examiner has identified though the ad and substantiated the reasons for rejections.

### ***Conclusion***

6. No claims are allowed.

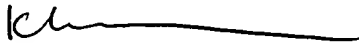
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S. Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith can be reached on (571)-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1645

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).




Khatol Shahnian-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645

December 29, 2005



MARK NAVARRO  
PRIMARY EXAMINER